

Science versus politics . . . in US needle exchange program

It was a classic case of science versus politics—and politics won. Armed with an overwhelming body of research establishing the value of needle exchange programs in reducing the spread of HIV without encouraging illegal drug use, US Health and Human Services (HHS) Secretary Donna E. Shalala was poised to announce on April 20th that the Clinton Administration would push for government funding of such programs as part of an overall HIV prevention strategy.

Yet moments before Shalala made the announcement, President Clinton, changed his mind: the administration would support the science but would not back it with federal money. Clinton's domestic policy advisers, it appears, had warned of a losing battle with Congress.

The HHS Secretary had been under heavy pressure to remove the ban on federal funding of needle exchange imposed by Congress in 1988. Her position was bolstered by a memo signed by Surgeon General David Satcher and National Institutes of Health (NIH) directors Harold Varmus, Anthony Fauci (NIAID), Alan Leshner (NIDA) and Claire Broome of the Centers for Disease Control and Prevention, who are unanimous in their belief that the research supporting needle exchange is overwhelming and without dispute.

Nevertheless, retired general Barry McCaffrey, director of the office of National Drug Control, stood firmly against the proposal, insisting that such programs send the wrong message about drug use. It became clear that Congress was behind McCaffrey and his argument prevailed. "These programs are magnets for all social ills—pulling in crime, violence, prostitution, dealers and gangs and driving out hope and opportunity," announced McCaffrey.

Although some studies do show that needle exchange does not completely eliminate HIV infection within the drug injection community—a study reported in April by Dutch researchers concluded that if HIV is to be beaten in this group, efforts should focus on the prevention of injection drug use itself (*AIDS*, 12; 625–633, 1998)—numerous studies have shown exchange to drastically reduce infection levels without increasing drug use. In a consensus statement issued last year, the NIH and the Institute of Medicine agreed that the data in favor of exchange was solid and that its opposition in the US can not be justified on scientific grounds: *There is no longer doubt*

that these programs work, yet there is a striking disjunction between what science dictates and what policy delivers.

Many are furious that Clinton has allowed politics to prevail over science. "This is an excellent example of politicians

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using one issue to make a comment about something else," says Robert T. Schooley, chair of the Adult AIDS Clinical Trials Group Executive Committee. "Needle exchange is a medical issue that has nothing to do with increasing illicit drug use. Politicians, however, have used it as convenient shorthand for 'I'm against illicit drug use.'" Schooley, who is also chief of infectious diseases at the University of Colorado Health Sciences Center, is incensed: "the spread of HIV-1 through injection drug users is the primary route by which AIDS has made its transition to women and children in this country."

Scrambling to regain credibility on the

issue after the U-turn, White House officials claim that they feared a clash with Congress would dampen state and local efforts to establish or sustain exchange programs. It "would have been voted down immediately and you would have scared off the local people," says White House adviser Rahm Emanuel. Endorsing the science will promote local efforts to fund needle exchanges, even without federal dollars, he claims.

However, it was not the Clinton Administration's endorsement of science but rather its lack of financial support that prompted New York billionaire George Soros to respond immediately on hearing the news and pledge \$1 million in matching funds to finance exchange programs. Soros urged other individuals, philanthropic groups and local governments to similarly help fill the void. Still, AIDS activists predict that local programs will now founder without federal help. "The funding is barely there now," says James Loyce Jr., chief executive officer of AIDS Project/Los Angeles, "the local governments, such as Los Angeles and San Francisco, that have taken exchange on have already taken a big risk. This will only undermine the advocacy that's been done on the local level."

And like some of Clinton's other attempts at compromise, this one too—supporting the concept of exchange without financing it—appeared to backfire on him. Within days, the House of Representatives pushed through legislation that would ban federal funding of needle exchange programs permanently. Clinton will almost certainly veto the measure.

MARLENE CIMONS, WASHINGTON, D.C.

. . . and in HIV vaccine development

Within weeks of accusations by the dean of Public Health at Allegheny University, Jonathan Mann, that the National Institutes of Health (NIH) is violating human rights through its failure to test current HIV vaccine candidates in Phase III trials (*Nature*, 392; 527 1998), 75 of America's leading researchers and AIDS activists have retaliated publicly with a letter to *Science* (280; 803, 1998). The letter encompasses points made in a commentary last month by John Moore, Aaron Diamond AIDS Research Center and Dennis Burton, Scripps Institute (*Nature Med. Vaccine Supplement*; 495, 1998).

This latest action typifies the battle between science and politics in the field of HIV vaccine research. On the political side is the President's Advisory Committee on HIV/AIDS (PACHA), which Mann was addressing when he made his remarks and which favors a transfer of responsibility for the development of an HIV vaccine from NIH to a different federal agency (*Nature Med. Vaccine Supplement*; 477, 1998). The view of the scientists, however, is that the NIH is the best organization through which to channel development of a vaccine.

It appears that Mann's comments were the spark to an already volatile situation.

"There would be no need to write a letter about this if it were not for the inflammatory statements made by Jonathan Mann which aren't based on science," says signatory Robert Doms, University of Pennsylvania. Ralph Steinman from Rockefeller believes that "Mann has greatly distracted from the very real effort going on to intensify vaccine research."

In an interview with *Nature Medicine*, Mann claimed to be pleased that the debate is out in the open, but insisted that the remarks attributed to him have been taken out of context. He said that the letter gave a "biased interpretation" of his testimony to PACHA and maintains that he is not calling for NIH removal from the project, merely its supervision by another body that would be prepared to push ahead with empirical trials.

Mann was also reported to have labeled David Baltimore, who heads a commission on HIV vaccine development, and NIH director Harold Varmus as 'incompetent,' but strongly denied such a slur on two scientists for whom he has "great respect." Needless to say, the letter was a demonstration that many of the country's top AIDS researchers are fully behind the two. Those questioned heaped praise on the Bal-

timore Commission for its funding of innovative research, the quality of its members and the fact that it travels around the country seeking opinions on vaccine development. "They're asking hard questions and are being very inclusive," said one researcher.

Like Mann, PACHA argues for empirical testing of vaccine candidates, such as the gp120 subunit vaccine, on the grounds that this approach has yielded successful vaccines in the past. Meanwhile, the scientists are adamant that there is no vaccine currently available that is worthy of testing.

"The gp120 subunit vaccine strategy was developed years ago," sighs Doms. "In the meantime, our understanding of HIV biology and antigenic structure has increased tremendously and in my opinion the gp120 vaccines are a complete waste of time, effort and resources." Doms illustrates what he and others regard as the futility of testing the vaccine with the more recent knowledge of the role of chemokine receptors: "Subunit vaccines are directed against T-tropic viruses that use the CXCR4 co-receptor and are not even the viruses that are transmitted from person to person."

Surprisingly, activist Derek Link of Gay Men's Health Crisis, whose boss Ronald

Johnson is a PACHA member, also signed the letter. "Although we want a vaccine as fast as possible, wishing it so doesn't make it so," says Link who prefers to trust the judgement of the country's best scientists as to whether there is a suitable candidate for large scale testing. He adds a concern that is common to the group of signatories: "There isn't an infinite number of HIV-infected people available, they are a valuable resource and it would create a lot of ill-will if a test goes wrong."

Link also raises an interesting caveat: "Right now most activists and HIV/AIDS patients are not plugged in to vaccines. In fact, a Kaiser Permanente questionnaire of [an ethnic group of patients] showed that 13 percent and rising believe that there is already a vaccine available to prevent AIDS." But that situation is changing. May 18th was the first HIV/AIDS Vaccine Awareness Day in recognition of the 2,750 US volunteers who have so far participated in preventive vaccine trials. As the AIDS community's understanding and interest in vaccine development grows, the opinions of both PACHA and the researchers may be drowned out by a force renowned for its ability to get things moving in this arena.

KAREN BIRMINGHAM, NEW YORK

Bill paves the way for more birth defects research

A bill signed into law by President Clinton on April 21st authorizes a substantial increase in federal funding for research into birth defects and opens the door for new initiatives in the future.

Representative Solomon Ortiz (D-Texas) has been pushing for passage of the bill since 1992, after a cluster of birth defects occurred in his district. While the cause of that outbreak still has not been determined, the measure has served to educate legislators about this category of conditions—the leading cause of infant mortality in the United States.

The new legislation calls for a budgetary increase this year to \$30 million from the \$26 million that Centers for Disease Control and Prevention (CDC) currently receives through appropriations bills that were passed as an interim measure, and for \$40 million next year. Getting that money to scientists though, will require an additional act of Congress. "This is really an authorization bill, so there's no money here [yet]. It authorizes the program. Funding comes through a different source," explains Joanne Merrill, a spokesperson for

the March of Dimes, a nonprofit organization which lobbied strongly for the bill's passage. The practical effect of the bill is to define the goals of the program, establish its political legitimacy and help secure future funding.

The new bill endorses coordinated, federally-funded research into the biology and epidemiology of birth defects and also calls for efforts in education and prevention to be stepped-up. The program will be managed by the CDC and will focus initially on eight regional centers scattered across the country, including one based at the CDC, which are already set up to study birth defects.

A group of scientists is being assembled under the title of National Birth Defects Prevention Network, to share information and standardize the methods used in studies of birth defects. "In this country, there's been no central funding mechanism to help set up studies of birth defects. Sometimes there are 50 different opinions of how that ought to be done," with each state pursuing its own approach says Larry Edmonds, Associate Chief of State Services in the Birth

Defects and Developmental Disabilities Branch of the CDC.

Researchers have hailed the measure as a much-needed boost for work in a neglected area of medicine. "I think it's long overdue. There's an incredible need for further research and understanding as to the mechanisms involved [in birth defects]," said Mike Artman, director of pediatric cardiology at the New York University Medical Center. Like others in the field, Artman hopes that the new legislation will pave the way for similar projects at other agencies: "This hopefully will turn the spotlight on and get people's attention so that we can move forward."

ALAN DOVE, NEW YORK

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Courtesy of March of Dimes